**To,** **Date: 00-XXX-0000**

Name of PI
Principal Investigator

Designation

Regional Institute of Ophthalmology,

88 College Street, Kolkata-700073,West Bengal, India

**PROTOCOL TITLE:**

**Protocol Number:**

# Subject: Ethics Committee Approval Letter for the above mentioned Study

Dear Name of PI,

The Institutional Ethics Committee, Regional Institute of Ophthalmology has reviewed and discussed the submitted documents by you on 00-xxx-0000 for the **“ “**

Study Protocol.

Following Study documents were reviewed by the Institutional Ethics Committee:

|  |  |
| --- | --- |
| **Sr. No** | **Study Documents**  |
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The list of Ethics Committee members who attended the meeting on 00-xxx-0000 at 0:00 am/pm at Seminar Room, Regional Institute of Ophthalmology, Kolkata-700073, West Bengal, India.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sr.****No.** | **Name** | **Qualification with Specialization** | **Current Organization** | **Telephone number, fax number, e-mail I.D, and mailing address** | **Designation/ Role of member in Ethics Committee** | **Affiliation of member with institute that has constituted the Ethics Committee** |
| 1 | **Dr. Santanu Sen** | MBBS,D.O, M.S,(Ophthalmology),PhD(Ophthalmology) | Visiting Consultant, Indian Statistical Institute, Kolkata)  | 9433103348drsantanusen@gmail.com | Chairman | EC Chairperson (Outside the Institute) |
| 2 | **Dr. Purban Ganguly** | MBBS,M.S(Ophthalmology) | RMO cum Clinical Tutor, Regional Institute of Ophthalmology, 88, College Street, Kolkata – 700073 | 9830558823Drpurban85@gmail.com | Member- Secretary | EC Member Secretary,RMO cum Clinical Tutor, Regional Institute of Ophthalmology |
| 3 | **Dr. Lakshmi Kanta Mondal** | MBBS,M.S,(Ophthalmology),PhD(Ophthalmology) | Professor, Regional Institute of Ophthalmology, 88, College Street, Kolkata – 700073 | 9830830216Lakshmi.mondal62@gmail.com | Clinician | EC Member,Clinician,Professor, Regional Institute of Ophthalmology |
| 4 | **Dr. Manab Nandi** | MBBS,MD(Pharmacology)M.Phil(Regenerative Medicine) | Associate Professor, Medical College, Kolkata, 88, College Street, Kolkata – 700073 | 9830835743manabn@gmail.com | Basic Medical Scientist | EC Member,Basic Medical Scientist,(Outside the Institute) |
| 5 | **Mr. Rajesh Arora** | B.Sc | Member of Swasthya Sankalp, 12, Kyd Street, Kolkata | 9331016096rajesharora@gmail.com | Scientific member | EC Member,Scientific member,(Outside the Institute) |
| 6 | **Mandabi Bhattacharrya** | M.Sc (Psychology) | Psychologist, baul Mon, 34, Jadavpur, Central Rd, Golf Green, Kolkata, West Bengal – 700032 | 9475218866Mandabi.ju@gmail.com | Social Worker | EC Member,Social Worker (Outside the Institute) |
| 7 | **Mr. Rakesh Arora** | B.Com | Businessman, Blue Cross Surgical Co., Kolkata – 700073 | 2234-8067/2221-5273 | Lay Person | EC Member,Lay Person,(Outside the Institute) |
| 8 | **Suparna Ray** | B.Sc,B.A.L.L.B | Advocate, Calcutta High Court | 9831105688Chatterjeesuparna878@gmail.com | Legal person | EC Member,Legal Person,(Outside the Institute) |

The documents were approved by IEC unanimously. No voting procedure has been done.

The IEC follows ICH-GCP, New Drugs and Clinical Trial Rules 2019, National Ethical Guidelines for Biomedical and Health Research involving human participants 2017 and all applicable regulatory guidelines.

You are requested to inform the following to the ethics committee:

* Any changes or deviations to the protocol approved by this ethics committee that you may implement to eliminate hazards to the trial Subject.
* Any changes in the patient information / Informed consent.
* All Serious adverse event
* New information that may affect adversely/safety of the subjects or the conduct of the trials

You are requested to inform the Institutional Ethics Committee of any amendments in the protocol for which a fresh approval needs to be taken.

You are required to submit a progress report half yearly and a final study report at the end of the study.

Thanking you,
Yours Sincerely,

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**Signature & Date**

Dr. Purban Ganguly
Member Secretary,

Institutional Ethics Committee

Regional Institute of Ophthalmology

88, College Street, Kolkata – 700073,
West Bengal, India